DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
FAX: 407-475-4769

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-03-24

March 6, 2003

Larry Smeal, Jr.
Smeal Trucking, Inc., and
Central Florida Calf Farms, Inc.
860 US Hwy. 98
Frostproof, Florida 33843

Dear Mr. Smeal:

An investigation of your activities conducted by our investigator Melissa Hill beginning on December 11, 2002 through January 17, 2003, confirmed that you offered several animals for sale for slaughter as food in violation of sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act.

On or about October 2, 2002, you sold a calf, identified by ear tag number G-648 and USDA serial number 410632 for slaughter as human food by [redacted] USDA analysis of tissue samples collected from that animal identified the presence of Tilmicosin in the liver, muscle and kidney of the animal at levels of 7.13, 2.83, and 6.45 ppm, respectively. A tolerance of 1.2 ppm has been established for residues of Tilmicosin in the edible tissues of cattle. The presence of this drug in edible tissue from this animal causes the food to be adulterated.

On or about October 22, 2002, you sold a calf, identified by Plant ID number 8320 (no back or ear tags present) and USDA serial number 410631 for slaughter as human food by [redacted] USDA analysis of tissue samples collected from that animal identified the presence of Penicillin in the kidney of the animal at a level of 0.12 ppm. A tolerance of 0.05 ppm has been established for residues of Penicillin in the edible tissues of cattle. The presence of this drug in the edible tissue from this animal causes the food to be adulterated.

On or about December 2, 2002, you sold a calf, identified by back tag number 58FV2301 and USDA serial number 410636 for slaughter as human food by [redacted] USDA analysis of tissue samples collected from that animal identified the presence of Penicillin and Neomycin in the kidney of the animal at levels of 0.51 and 8.97 ppm respectively; and Sulfa di-methoxine in the liver of the animal at a level of 0.22 ppm. A tolerance of 0.05 ppm for Penicillin, 7.20 ppm for Neomycin, and 0.10 ppm for Sulfa di-methoxine has been established for these drugs in the edible tissue of cattle. The presence of these drugs in the edible tissue from this animal causes the food to be adulterated.

Investigator Hill has made numerous attempts to contact you by phone and in person. Her one telephone conversation with you determined that you were aware of the initial two incidents of illegal drug residues found in calves you have offered for slaughter. You also stated that you do not receive records from your calf suppliers. Further attempts to contact you have gone unanswered. A visit to your place of business/residence determined that you have facilities to hold calves for a period of time. It is your responsibility to assure that cattle you present for slaughter for human consumption either are not medicated or are withheld for the prescribed period of time. It is further your responsibility to assure that proper identification, such as back or ear tags are present on any animals you deliver to slaughterhouses so that they may be tracked for illegal drug residues.

This letter is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for assuring that your overall operation and the food you distribute are in compliance with the law.

You should take prompt action to correct these violations and to establish procedures to prevent their recurrence. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Federal Food, Drug, and Cosmetic Act. The fact that you sold an adulterated animal to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step taken to correct the violations and prevent the recurrence of similar violations. If corrections cannot be completed within (15) working days, state the reason for the delay and the time frame within which the corrections will be completed. Also include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to Martin E. Katz, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, telephone (407) 475-4729.

Sincerely,

Emma R. Singleton
Director, Florida District